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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES

DATE: January 7, 2009

LOCATION: Los Angeles International Airport
Samuel Greenberg Board Meeting Room
1 World Way
Los Angeles, CA 90045

BOARD MEMBERS PRESENT: Robert Graul, RPh, Chairperson
Andrea Zinder, Public Member, Chairperson
Robert Swart, PharmD

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Tessa Fraga, Administrative Analyst§
Tina Thomas, Enforcement Analyst

Chairperson Graul called the meeting to order at 1:07 p.m.

Regulation Report

1. Board Approved Regulation – Undergoing Administrative Review

Amend Section 1760 – Disciplinary Guidelines

Chairperson Graul provided a brief status update on the pending regulation change. At the April 2008 board meeting, the board voted to adopt a regulation change to amend Title 16 California Code of Regulations (CCR) section 1760 – Disciplinary Guidelines. After receiving additional clarifying comments from counsel, board staff submitted the completed rulemaking to the Department for review and approval in September 2008. While the department did approve this regulation, State and Consumer Services Agency is concerned about the optional language relating to automatic revocation when a

probationer fails to submit cost recovery as mandated. As a result, it is being brought back to the board for further consideration.

Executive Officer Herold provided a staff recommendation that the committee consider removing the one "optional term" to allow the board to continue to pursue the remaining changes of the Disciplinary Guidelines.

MOTION: Support to move forward with a 15-day notice as recommended,

M/S: RS/AZ

SUPPORT: 3 OPPOSE: 0 ABSTAIN: 0

2. Board Approved Regulations – Previously Noticed (Not for discussion at this meeting)

Chairperson Graul indicated that these items are not for discussion for the committee.

Chairperson Graul briefly discussed the two changes by title only.

a. Proposed Repeal of 16 CCR sections 1716.1 and 1716.2 and Amendment to 16 CCR sections 1751-1751.8 and Adoption of 16 CCR sections1735-1735.8

Currently, pharmacy law provides the authority for a pharmacist to compound drug products and compound sterile injectable products. As required in Business and Professions Code (B&PC) section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that engage in general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

The 45-day comment period began in September 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing. The subcommittee will be providing recommendations for consideration and action by the board at the January 2009 Board Meeting.

b. Proposed Amendment to 16 CCR section 1773 and Adoption of 16 CCR section 1773.5 – Ethics Course.

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement discipllne option. Based on their discussion and work, the subcommittee recommended that the board vote to create a program similar to the program used by the Medical Board. This proposal would

establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements were necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional eight hours of time to allow the pharmacist to complete self-reflection on the decisions that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" in proposed section 1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, the board authorized the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to section1773 as filed and adopt section 1773.5 of the proposed regulations with this modified text.

The 15-day comment period is over, and no additional comments were received. Board staff will begin compiling the rulemaking and will submit it to the department during the first quarter of 2009.

3. Board Approved Regulations – Awaiting Notice

Chairperson Graul provided an update on board approved regulations that are awaiting notice.

a. Proposed Amendment to 16 CCR section1715 and 16 CCR section 1784 - Section 100 Changes to Update the Self Assessment Forms for Pharmacies and Wholesalers

Section 1715 establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. Section 1784 establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure

compliance with pharmacy law. These self-assessment forms are designed to assist pharmacies and wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the forms make the pharmacy inspection process more meaningful and educational and provide relevant information to pharmacies and their PIC.

Chairperson Graul noted that staff will compile the section 100 regulation change package in the first quarter of 2009.

b. Proposed Addition to 16 CCR section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

The adoption of CCR section 1785 would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations, thereby increasing public safety as a result.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Chairperson Graul advised that a copy of the draft language and form is provided, however board staff do not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

c. Proposed Adoption of 16 CCR section 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies and was approved at the July 2007 Board Meeting. The board voted to move this proposal.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

d. Proposed Amendment to 16 CCR sections 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR sections 1721 and 1723.1 which would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

Chairperson Graul advised that a copy of the language as approved by the board was provided in the meeting materials.

4. Proposed Regulation Language for Board Discussion and Possible Action

Chairperson Graul advised that these items were previously discussed during the meeting, as they were included on the agenda twice.

5. Regulations Under Development

a. Proposed Amendment to 16 CCR section 1780 – Update the USP Standards Reference Material

Chairperson Graul provided a brief synopsis of the proposed change to CCR section 1780, which sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to section1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Chairperson Graul highlighted that because of stated concerns about whether referencing the 2005 USP standards would be an unreasonable burden on wholesalers, the board voted (October 2008) to address the issue of updating the USP Standards reference materials within this section.

President Schell and Committee Chairperson Bob Graul are serving on the subcommittee and will be working with board staff and industry. Chairperson Graul requested volunteers to work with the subcommittee to address any potential concerns. Kaiser, California Society of Health-Systems Pharmacist and Western Medical Center -

Santa Monica will each have a representative serve on the subcommittee. Ms. Herold indicated that she will also contact Healthcare Distribution Management Association for volunteers.

Chairperson Graul requested that board staff review the Pharmacy Law book for additional references in advance of the first subcommittee meeting.

b. Proposed Amendment to 16 CCR section 1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member does not seek reimbursement for his or her time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member's term is generally about eight years.

Legislative Report

At the request of the Chairperson, Ms. Herold provided an overview of the Legislative Process.

The two year Legislative cycle began in December 2008. About one-third of the representatives are new. The board works hard to keep pharmacy law current. Beginning in December 2008, a special session was called to deal with the budget crisis. To date, this special session has not yielded any results. Legislatively, all items will revolve around the resolution of budget issues. Ms. Herold provided key dates on the Legislative calendar including the February 27, 2009, bill submission deadline. All bills are subject to review by, at minimum, a policy committee and if appropriate, a fiscal committee. All bills must be passed out of the house of origin by June 5, 2009. All bills must be passed by the second house by September 11 to move to the Governor. If the bill is enacted, unless otherwise specified, the bill will go into effect on January 1, 2010.

Ms. Herold also noted that bills which don't make it out of the house of origin by the established deadline can become a two-year bill.

1. Legislation Sponsored by the Board of Pharmacy Omnibus Provisions from 2008

Chairperson Graul indicated that at the October 2008 Board Meeting, the board voted to pursue all omnibus provisions that were vetoed by the Governor in SB 1779 (Senate Business and Professions Committee).

These omnibus provisions were categorized into four types of changes:

1. Use of mobile pharmacies.
2. Changes resulting in a comprehensive legal review by board staff and counsel on the legal requirements surrounding the Pharmacist-in-Charge and Designated Representative-in-Charge.
3. General omnibus provisions.
4. Omnibus provisions resulting from the recodification of Business and Professions Code section 4052.

Public Comments:

Clarification was requested on the costs to implement these provisions.

Ms. Herold responded that the cost would be negligible, as the majority of the changes are non-controversial and non-substantive.

Dr. Swart sought clarification about the changes to B&PC 4062 and 4110 which would allow for the use of a mobile pharmacy if the pharmacy was being remodeled. Ms. Sodgergren advised the committee that this change is not reflected because the Senate Business and Professions Committee, author of the omnibus bill, stated that although the committee will again author the omnibus bill, it will not allow for any changes to the provisions contained within SB 1779.

a. Omnibus Provisions for 2009

Chairperson Graul also discussed the omnibus provision for 2009. At the October 2008 Board Meeting, the board voted to pursue several new omnibus provisions.

Add Section 4146 – Disposal of Returned Sharps by a Pharmacy
This section needs to be added to allow a pharmacy to accept returned sharps containers from consumers for disposal.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4401 – Pharmacists: Biennial Renewal
This section needs amendment to require pharmacists to notify the board of any misdemeanor or felony conviction or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

Amend Section 4403 – Reissuance Without Payment of Fees Prohibited
This section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony conviction or whether any disciplinary action has been taken, as specified, subsequent to the licensee's last renewal.

b. Immunization Proposal – Amendment to Business and Professions Code 4052 and Adoption of 4052.8

Chairperson Graul stated that at the October 2008 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP).

Beginning in November 2007, board staff worked with stakeholders to address questions and elicit support for this proposal for sponsorship in 2008. However, after consideration in April 2008, it was decided not to move the proposal that year due to a lack of staff as well as other legislative priorities.

Board staff is contacting potential authors for this proposal and will resume stakeholder meetings in February 2009 to solidify a broad base of support for this proposal.

Chairperson Graul indicated that copies of the proposed language and the ACIP Adult and Adolescent Immunization Schedules were included in the committee meeting materials.

Committee Comments:

Ms. Zinder questioned whether the board will be able to find an author in 2009.

Ms. Herold explained why the bill was not pursued last year and said that the board has support from both the California Pharmacists Association and the California Retailers Association. Ms. Herold underscored that this proposal is an important public health bill and ensures important training requirements.

Chairperson Graul confirmed that the key to this proposal is to solidify stakeholder support.

Dr. Swart offered to provide contact information of a pharmacist who has experience in community immunizations to assist the board.

c. Elements of a Prescription Label – Amendment to Business and Professions Code section 4076

Chairperson Graul stated that the board voted (October 2008) to pursue a statutory change to replace the "condition" for which a prescription is prescribed, with the "purpose" for which the medicine is prescribed. This change will clarify a pharmacist's authorization within (B&PC) section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient, if requested by the patient. This proposal is consistent with the results of the board's prescription label survey where approximately 25% of all respondents requested the purpose of the medicine be included on the label. Purpose removes the onus from the physician to provide the condition.

Committee Comments:

Dr. Swart stated that he was opposed to this proposal at the October 2008 meeting because of concerns with the implementation of such a change. At that time, Dr. Swart was concerned that providing the purpose could cause a delay in providing a consumer's prescription because of the current workflow in pharmacies. Dr. Swart requested structuring the requirement to allow for a line on the prescription label where the purpose can be handwritten by the pharmacist.

Ms. Herold responded that the requirement is non-prescriptive, and the pharmacy can determine how to implement the change. She stated further that Dr. Swart's concern can possibly be addressed through the board's efforts to implement SB 472, the standardization of the prescription label. Ms. Herold indicated that staff will confirm this option with legal counsel.

Public Comments:

Steve Gray (Kaiser Permanente and the Pharmacy Foundation of California) voiced support for this proposal, as it allows for a dialog between the pharmacist and patient. Dr. Gray also stated that as the profession moves forward with electronic prescribing, the law will need to allow for the medication's purpose to be collected as part of the workflow.

Based on a question from the public regarding the actual change in the proposal, Chairperson Graul stated that the medication's purpose can be typed on the label and that if the pharmacist is unclear of the purpose of the medicine, the pharmacist may seek clarification from the patient or contact the physician to ascertain the appropriate purpose. Chairperson Graul stated that, ideally, all physicians would provide the purpose of the prescription: however, imposing that requirement is outside the scope of the board's jurisdictions.

Ms. Herold amplified why this is such an important consumer protection change.

Amy Gutierrez, representing LA County asked how a change would be reconciled, procedurally, if a condition for which a medicine is prescribed is changed over time.

Ms. Herold responded that the goal is to achieve better patient outcomes.

2. Legislative Proposal Regarding Return of Medicine to Reverse Distributors

Chairperson Graul indicated that this is an action item for the committee to determine if the proposal should be an added item to the Legislative calendar for 2009.

Ms. Herold provided background on the proposal, stating that over the last two years, the board has been working with sponsors of drug take-back programs to ensure the appropriate disposal of unused medications. Once drugs are aggregated, they are carried back by an integrated waste hauler. Ms Herold said that our law allows a pharmacy to return drugs to a wholesaler only if the drugs are going back into the drug supply, not for destruction. If drugs are to be destroyed or returned for credit, they must be returned via a reverse distributor. The proposed packet defines the criteria for a reverse distributor to perform these functions.

Chairperson Graul discussed each change by code section.

Ms. Zinder asked for clarification on the role of a reverse distributor.

Ms. Herold responded that a reverse distributor will either destroy them via incineration or send them to in integrated waste hauler for destruction.

Dr. Swart stated that most reverse distributors are disposing of the product.

Dr. Swart suggested that the proposal allows for an estimated quantity in B&PC section 4081(b). Ms. Herold suggested that staff survey some drug manufacturers to identify how they currently determine the quantity.

Ms. Quandt (Longs/CVS) voiced concern about the proposed separation of the drugs dispensed to the patient, and later returned because of a prescription error, from those that are never dispensed. Ms. Quandt advised that in the case where a prescription was erroneously provided to a patient, it could be problematic to arrange for the destruction of the product if is it considered pharmaceutical waste. She sought clarification that a pharmacy that is not participating in the drug take-back program would need to contact a reverse distributor directly to dispose of any drugs which were a result of a medication error.

Dr. Gray (Kaiser Permanente) suggested that the committee may want to consider a change to section 4126.5 (a)(6) to specify who is included in that subsection. Dr. Gray also suggested changing the language to include any entity licensed by the board, and state that the change will help to clarify how such entities are supposed to handle the drugs.

MOTION: To recommend to the board the addition of this proposal to amplify regulatory structure of reverse distributors to the board's Legislative calendar for 2009.

M/S: AZ/RS

VOTE: 3 OPPOSE: 0 ABSTAIN: 0

3. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

Chairperson Graul provided a brief overview of two legislative proposals that were introduced impacting the practice of pharmacy.

a. AB 67 – Nava

This bill would establish the Pharmacy Patient Protection Act of 2008, which would require pharmacists to dispense all lawfully obtained prescriptions when the prescribed medication is in stock without regard to any ethical, moral, or religious objections.

b. SB 26 – Simitian

This bill would require the board to coordinate with other state agencies, local governments, drug manufacturers, and pharmacies to develop sustainable, efficient policies and programs to manage pharmaceutical wastes and the disposal of devices. The bill would authorize a pharmacy to accept the return of home-generated pharmaceutical waste and home-generated sharps waste, as defined.

Chairperson Graul indicated that copies of the bills were included in the committee meeting materials. He stated that part of the reason for the legislative overview was to highlight that it is early in the session and, thus, too early to make positions by the committee.

Ms. Zinder agreed that it is early in the session but also expressed concern about AB 67 (Nava).

Ms. Herold indicated that we are uncertain why this proposal is directed at pharmacists.

Dr. Swart stated that AB 69 is written with a broad stroke and would take away a lot of professional judgment by the pharmacist. Dr. Swart state that the board needs to watch this bill, as it appears problematic.

Ms. Herold stated that board staff will seek clarification from the author's office on the proposal.

Dr. Gray requested clarification of whether the proposal (AB 69) nullifies some of the requirements of B&PC section 733 and stated that it appears all other provisions within section 733 remain in effect.

Board staff indicated that they will seek clarification from counsel.

4. Public Comment for Items Not on the Agenda

Chairperson Graul reminded the committee that it cannot discuss any of these items.

Dr. Gray requested that the board consider a modification to Health and Safety Code section 11166 where it makes reference to 11164. Dr Gray state that section 11164 is no longer relevant and the reference is confusing to pharmacists.

Additionally, Dr. Gray discussed B&PC section 4425 which includes a statement that the Department of Health Services (DHS) (now the Department of Health Care Services) is required to provide pharmacies with a poster defining Medi-Cal pricing. Dr. Gray suggested that the board have a discussion with DHS about this requirement, as DHS has never provided these posters, and pharmacies are being sued for failure to provide the information as required in B&PC section 4425.

A representative from the Drug Policy Alliance (DPDP) provided an overview of the statewide program. She explained that the program is adopted on a county-by-county basis. She indicated that Los Angeles County has the most successful program thus far within the state as a result of substantial support and involvement from the pharmacists within the county. Ms Garcia stated that DPDP also takes a proactive role in syringe disposal. She provided the program website, *helpstopaids.com*. She thanked the board and the pharmacist community for their continued support. Ms Garcia advised the committee that the DPDP will sunset in 2010 unless they are reauthorized next year to be able continue to provide low-cost access to the pharmacists who depend on the program.

Supervising Inspector Ratcliff recommended that the committee review the requirements in CCR section 1707.2 that define the minimum components of patient consultation. Dr. Ratcliff stated that changes to this regulation section may help underscore the importance of the consumer understanding the purpose of a prescribed medicine.

Chairperson Graul requested that all legislative and regulatory proposals be provided in writing to the board for consideration.

The meeting was adjourned at 2:11 p.m.